

ANTI-ITCH EXTRA STRENGTH- diphenhydramine hydrochloride, zinc acetate cream
Personal Care Products, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredients

Drug Facts

Diphenhydramine hydrochloride 2%

Zinc acetate 0.1%

Purpose

Topical analgesic

Skin protectant

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Uses

For the temporary relief from pain and itching associated with:

- insect bites
- sunburn
- minor skin irritations
- minor burns
- scrapes

Dries the oozing and weeping of

- poison ivy
- poison oak
- poison sumac

Warnings

For external use only

Do not use:

- on large areas of the body
- with any other product containing diphenhydramine, even one taken by mouth

Ask a doctor before use

- on chicken pox
- on measles

When using this product avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- symptoms persist for more than 7 day or clear up and occur again within a few days

Directions

- do not use more than directed
- adults and children 2 years of age and older, apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor
- use daily for 4 weeks

Other information

- store at temperature between 58° - 77° F (15° - 30° C)
- do not use if seal on tube is punctured or missing

Inactive ingredients

cetyl alcohol, diazolidinyl urea, methylparaben, PEG-2 stearate, PEG-20 stearate, propylene glycol, propylparaben, purified water

Product Label

DRUGSTORE-Rx

SMART WELLNESS

Extra Strength

Anti-Itch Cream

Topical Analgesic and Skin Protectant

Histamine Blocker

Relieves itching from

- * Poison ivy
- * Poison sumac
- * Sunburn
- * Insect bites

NET WT. 1.25 OZ. (35 g)

DRUGSTORE-Rx

SMART WELLNESS delivers outstanding quality in healthcare products, at truly amazing prices. We employ the highest standard when searching the world to bring the best value to your doorstep. Use our products confidently, knowing that attention and care has gone into every item. That's smart wellness!

Distributed by: PERSONAL CARE PRODUCTS, LLC
Troy, Michigan 48084 U.S.A.

Code No. MH/DRUGS/KD-313

Made in India

DRUGSTORE-Rx
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& Skin Protectant

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Drug Facts (continued)

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ANTI-ITCH EXTRA STRENGTH

diphenhydramine hydrochloride, zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-2437
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	700 mg in 35 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	35 mg in 35 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-2 STEARATE (UNII: 94YQ11Y95F)	

PEG-20 STEARATE (UNII: NBX892EA57)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-2437-1	35 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/10/2013	

Labeler - Personal Care Products, Inc. (966155082)

Registrant - Personal Care Products, Inc. (966155082)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd.		916837425	manufacture(29500-2437)

Revised: 7/2013

Personal Care Products, Inc.